



December 23, 2003

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Comments to Docket No. 02N-0276, Interim Final Rule on  
Registration of Food Facilities Under the Public Health Security  
and Bioterrorism Preparedness and Response Act of 2002

Dear Ladies and Gentlemen:

This comment is submitted by Yellow Transportation (Yellow), one of the leading less-than-truckload (LTL) freight motor carriers in the United States. Yellow operates a fleet of approximately 7,900 trucks and 34,700 trailers, and utilizes about 350 terminal sites to consolidate freight from multiple locations in order to efficiently transport the cargo to the various ultimate destinations. We urge the FDA to clarify its interpretation of the term "facility" by treating these terminal sites as exempt from the statutory requirement for registration of food facilities, on the basis that they constitute the holding of food incidental to the carrier operations and as such, in the usual course of business as carriers.

1. The LTL freight consolidation terminal sites are merely incidental to the movement of the mobile facilities used to transport food, and any holding that occurs at such terminals is in the usual course of business as a carrier

In the Interim Final Rule, the agency acknowledges that in the legislative history of the Bioterrorism Act, the Congress intended to exclude motor carriers from registration. The Conference Report states:

In addition, the Managers intend that, for purposes of this section, "facility" does not include trucks or other motor carriers, by reason of their receipt, carriage, holding, or delivery of food in the usual course of business as carriers.

H.R. Conference Report No. 481, 107 Cong., 2d Sess., 134 (2002)

Query, what constitutes "holding in the usual course of business of a carrier"?

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It is important that Congress, in the Conference Report, uses the term motor carrier as opposed to motor vehicle. A motor vehicle is defined by the Federal Motor Carrier Safety Administration as follows:

Motor vehicle means any vehicle, machine, tractor, trailer, or semi-trailer propelled or drawn by mechanical power and used upon the highways in the transportation of passengers or property.  
49 C.F.R. §390.5.

A commercial or “for-hire” motor carrier is a more inclusive term as it is the person or business engaged in the transportation of goods for compensation. *Id.* Thus, it includes all aspects of the transportation of goods, including the holding of goods incidental to its transportation in various ways. The Congress, the Department of Transportation, the transportation industry, and others recognize and operate on this distinction. In its interpretation of the statute, FDA should recognize this distinction as well.

From a factual and practical standpoint, “holding” for a trucking operation includes not just cargo residing in a mobile vehicle, rest stops or overnight truck stops, but it commonly, and particularly for LTL type of operations, includes freight consolidation and concomitant transfer operations at a designated terminal site to expedite the cargo delivery to its destination. That is, LTL (less-than-truckload) serves the individual needs of businesses that do not need a full truck load movement of their goods. Full truckload carriers simply pick up freight and transport it to its final destination. The LTL carriers pick up multiple shipments from various customer sources, sort the freight locally at a centralized terminal site and load it onto outbound trucks for transit, often to a terminal site near the place of destination for further sorting, reloading and delivery.

While we understand that the time period the freight remains at the terminal site is not relevant to the statutory approach to the term “hold”, nevertheless, at least with respect to Yellow’s operations, which we believe is relatively standard for LTLs, the average maximum freight stay at a small terminal is about 6 to 8 hours and the maximum freight stay at a large terminal site is about 12 to 14 hours – about the same as an overnight truck rest stop.

The nature of the LTL freight consolidation terminal site is irrelevant, and merely a convenience. The intent of the operation is not to “hold”; rather, the intent is the

opposite -- to transfer the freight and remove it from the site as swiftly as possible, in order to continue its journey to its destination. The truck terminal is not the destination. In fact, the term "terminal" is probably a misnomer. The term means an end point; that is "either end of a carrier line" (see Webster's New Collegiate Dictionary). The consolidation sites are not end points, but rather transit points for redirecting cargo to its destination.

The bills of lading used to move goods in transit reflect this fact. Initially, it is important to note that the bill of lading does not pass title to the goods, but only functions as a receipt for transportation of the goods from Point A to Point B. UCC § 1-201(6). The bill of lading designates a pickup and delivery location and does not reference the consolidation sites. The freight consolidation site operation is part of the movement of the freight, and the holding of the goods at a consolidation site is merely incidental to the transportation of the goods from Point A to Point B. Because it is part of the continuous movement of the freight, the consolidation terminal should be treated as part of the usual course of business of a carrier.

Further, as currently established, the FDA registration regulations appear to set up an unfair anomaly as between LTL carriers and full truckload carriers. A full truckload carrier may bring a full trailer to a terminal and hold the goods in the trailer for prolonged periods of time without having to register the terminal because the goods remain in the trailer and it is held in the trailer in the usual course of business as a carrier. Arguably, this may be longer than the time the goods are held at an LTL terminal for consolidation. However, because the goods are unloaded and reloaded at an LTL terminal, no matter the holding time, it is deemed to be a facility that needs to register. See 68 Fed. Reg. at 58933, Response to Comment 166.

2. Regulatory interpretations by the FDA and other relevant agencies support an exception for LTL terminals that hold food shipments as part of the usual course of business of a carrier.

a. Relevant past FDA regulatory interpretations

FDA has recognized the distinction between motor carriers and motor vehicles, in other regulatory venues. The FDA Investigations Operations Manual (Chapter 4, Sampling) uses the term carrier to mean a company, rather than a vehicle. Section 703 of the FDCA subjects "carriers" to inspection of interstate shipment records, and has application to a company, rather than a vehicle. Similarly, the statutory phrase "the

usual course of business of a carrier” should be the business of the company, and not of a vehicle.

Further, Section 703 of the FDCA exempts carriers from other provisions of the FDCA in exchange for FDA’s access to certain carrier records of interstate shipment:

... except that carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drug, devices or cosmetics in the usual course of business as carriers.

21 U.S.C. 373.

It is important to note that Congress, in drafting the Bioterrorism Act, was cognizant of this past treatment of carriers by the FDA because the Act states that nothing in the registration section of the Statute “shall alter or amend the treatment of carriers under section 703 of the [FDCA].”

Accordingly, because terminals are used in the usual course of business of carrier companies, these terminals should not be subject to the food facility registration amendments to the FDCA by reason of their incidental “holding” of food while in transit.

b. Other relevant regulatory interpretations

An approach that would exempt LTL terminals is consistent with and supported by the Department of Transportation, which has responsibility to ensure the safety of motor carriers. As an example, the approach is consistent with the regulatory definition of “transportation” used by the Department of Transportation (DOT) in its regulation of hazardous material.

According to the DOT rules on the handling of hazardous materials, the definition of “transportation” includes storage incidental to the movement of property:

Transports or Transportation means the movement of property and loading, unloading or **storage incidental to the movement.**  
(emphasis added) 49 U.S.C. 5102; 49 CFR 105.5 (b)

In subsequent documents on hazardous material transportation and hazard communication requirements, the DOT describes what is meant by “storage incidental to the movement” of materials:

Storage that is incidental to movement generally is storage that occurs between the time a hazardous material is offered for transportation and the time it reaches its destination and is delivered to the consignee. 68 Fed. Reg. 61905, 61907 (October 30, 2003). See also 68 Fed. Reg. 34880, 34886, (June 11, 2003).

Moreover, the DOT Interim Rule regarding Transportation of Household Goods covers “storage in transit” of goods (see 68 Fed. Reg. 35064, 6/11/03).

Finally, the definition of “transportation” mandated by Congress for motor carriers includes the use of a facility or warehouse related to the movement of property, as well as services related to that movement, such as transfers in transit, storage, and interchange of property (see 49 USC 13102 (19)).

Clearly, both the FDA and DOT regulatory schemes provide a reasonable basis to view LTL terminal site operations as a “holding” that is in the usual course of business of a carrier, and within the exception from registration for carriers.

3. A reasonable interpretation of the term “facility,” as defined and described in the Bioterrorism statute and in the FDA Interim Final Rule, would permit an exception for the LTL carrier operations site.

The term “facility” is defined and described in Section 305, Registration of Food Facilities, in a way that could reasonably be interpreted as excluding the freight consolidation sites of LTL carriers because they are merely incidental to carrier transportation, a category recognized as exempt from registration. The statute requires that the owner, operator or agent in charge of a facility engaged in manufacturing, processing, packing or holding food for consumption in the U.S. by humans or animals register that facility with FDA. The term “facility” is further delineated as:

The term “facility” includes any factory, warehouse, or establishment . . . that manufactures, processes, packs, or holds food.

Bioterrorism Act Sec. 305 (to be codified at 21 U.S.C. 415(a)).

LTL in-transit freight consolidation truck terminals do not fall under this definition of “facility.” First, we note that the term “terminal” is not referenced or included in the definition of the term “facility” in the Bioterrorism Statute or in the FDA Interim Final Rule.

Second, a freight consolidation terminal is not a factory. It does not perform the operations of a factory enumerated in the statute: manufacturing, processing or packing.

Third, a freight consolidation terminal is not a warehouse. The term “warehouse” is defined for purposes of interpreting the Federal Food, Drug, and Cosmetic Act (“FDCA”) by FDA in its *Regulatory Procedures Manual*, as a “private or public facility for the storage of consumer products, including products reshipped from the producer or grower to the manufacturer or other customer.” Unlike warehouses whose principal purpose is to serve as food storage facilities, truck terminals are structures that temporarily provide shelter to food being transferred to other motor vehicles while in transit.

Fourth, the term “terminal” does not fall within the FDA’s definition of an “establishment” for purposes of implementing the FDCA. The *Regulatory Procedures Manual* defines an “establishment” as a place of business or residence of a:

- A. **Grower:** Raises livestock, raw agricultural products, or aquacultural products for sale (farms, feedlots, dairy farms, and botanicals).
- B. **Manufacturer:** Firm or individual responsible for making a product.
- C. **Packer/repacker:** Packs a product or products into different containers without making any change in the form of the product. Includes packers of raw agricultural products and medical gas repackers.
- D. **Salvage Operation:** An establishment dealing primarily in the reconditioning and resale of damaged goods.

- E. Shipper:** Firm or individual responsible for introducing merchandise into interstate commerce by way of transport that does not act as a manufacturer, repacker, distributor, etc.
- F. Warehouse:** A private or public facility for the storage of consumer products, including products reshipped from the producer or grower to the manufacturer or other customer.

In conclusion, and in light of all of the above, LTL terminals engaged in the consolidation of freight function in the usual course of business as carriers and should be excepted from the registration requirements for food facilities.

Very truly yours,

A handwritten signature in black ink that reads "Mike Kelley". The signature is written in a cursive, flowing style.

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